

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:  
SANDFORD T. COLB & CO.  
P.O. BOX 2273  
76122 REHOVOT  
ISRAEL



NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 65343	Date of mailing (day/month/year)
International application No. PCT/IL 08/00646	International filing date (day/month/year) 11 May 2008 (11.05.2008)
Applicant METACURE LTD.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.
- Filing of amendments and statement under Article 19:  
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
- When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
  - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

### 4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US

Neil Slep PCT, Attn: ISALUS  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-273-4300  
PCT ODP: 571-273-3774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 65343	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/IL 06/00646	International filing date (day/month/year) 11 May 2006 (11.05.2006)	(Earliest) Priority Date (day/month/year) 09 May 2007 (09.05.2007)	
Applicant METAGURE LTD.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.  
☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1B  
☐ as suggested by the applicant.  
☐ as selected by this Authority, because the applicant failed to suggest a figure.  
☒ as selected by this Authority, because this figure better characterizes the invention.  
b. ☐ none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AL 08/00646

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/00 (2008.04)

USPC - 600/37

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC8 : A61F 2/00 (2008.04)

USPC : 600/37

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC8 : A61B 5/00 A61B 5/04 A61B 17/00 A61B 17/12 (2008.04)

USPC : 600/343 600/372 600/547 606/157 606/151 606/138

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubMed (PQPB,USPT,EPAB,JPAB), Google Scholar

solid liquid, determinis, handheld wireless pda, diary journal log, fundic, stomach, gastrointestinal tract, antrum, pylorus, activity ingestion monitor, sensor, force ingestis, regulas analys, party parials, surround, palc-s strip, constrictis, clip, otic's electrode, open 270

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/026499 A1 (GERTNER) 23 November 2008 (23.11.2008) see especially para [0141], [0149], [0156], [0160]-[0163] fig 11D	44-48
Y	US 2007/0027493 A1 (BEN-HAIM et al) 1 February 2007 (01.02.2007) see especially para [0149], [0173], [0174], [0176], [0177], [0186], [0189], [0191], [0193], [0199], [0205], [0209], [0225], [0248]	1-43
Y	US 2005/0086514 A1 (STARCKBAUM) 5 May 2005 (05.05.2005) see especially para [0018]-[0020], [0029], [0030]	1-8, 10-19, 22-34, 37-43
Y	US 5,168,104 A (WERNICKE et al) 23 February 1993 (23.02.1993) see especially col.10, in 29-44, col 14, in 1-9	6-43
Y	US 2008/0054037 A1 (SHALON et al) 23 March 2008 (23.03.2008) see especially para [0063], [0145], [0157], [0221]	35-43

☐ Further documents are listed in the continuation of Box C.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

17 October 2008 (17.10.2008)

Date of mailing of the international search report

28 OCT 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22312-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpline: 571-273-4300

PCT DBP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

# PATENT COOPERATION TREATY

IG AUTHORITY

: & CO.

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)		28 OCT 2008
FOR FURTHER ACTION		
See paragraph 2 below		
International filing date (day/month/year)	Priority date (day/month/year)	
11 May 2008 (11.05.2008)	09 May 2007 (09.05.2007)	
ion (IPC) or both national classification and IPC 3.04)		
TD.		

cations relating to the following items:

s of the opinion

rity

-establishment of opinion with regard to novelty, inventive step and industrial applicability

of unity of invention

soned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
ions and explanations supporting such statement

ain documents cited

tain defects in the international application

tain observations on the international application

ual preliminary examination is made, this opinion will be considered to be a written opinion of the  
Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority  
he IPEA and the chosen IPEA has notified the International Bureaux under Rule 56.1bis(b) that written  
nal Searching Authority will not be so considered.

ted above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA  
from examination, with amendments, before the expiration of 3 months from the date of mailing of Form

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 08/00646

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:  
☒ the international application in the language in which it was filed.  
☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any nucleotide and/or amine acid sequence disclosed in the international application, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ on paper  
☐ in electronic form
  - c. time of filing/furnishing  
☐ contained in the international application as filed  
☐ filed together with the international application in electronic form  
☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 06/00646

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-48	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-48	NO
Industrial applicability (IA)	Claims	1-48	YES
	Claims	None	NO

2. Citations and explanations:

Claims 44-48 lack an inventive step under PCT Article 33(3) as being obvious over US 2006/0264699 A1 to Gertner.

Regarding claim 44, Gertner teaches apparatus comprising:

- a) a gastrointestinal (GI) tract attachment element, configured to be coupled to a portion of a GI tract of a subject such that the element surrounds less than 360 degrees of the GI tract (para [0160]-[0163], fig. 11D, extragastric balloon 430 partially surrounds stomach and anchored in place), and
  - b) applies a constrictive force to the GI tract portion that causes a reduction in a cross-sectional area of the GI tract in a vicinity of the portion (para [0160]-[0163]); and
  - c) at least one electrode, coupled to the attachment element such that the electrode contacts the GI tract portion when the attachment element is coupled to the GI tract portion (para [0141], [0149]).
- Gertner does not specifically teach causing at least a 5% reduction in cross section. Gertner does teach a reduction in cross section (para [0160]-[0163]). It would have been obvious to one skilled in the art that Gertner could be modified as claimed through routine experimentation in order to adjustably restrict food intake or a patient by patient basis.

Regarding claim 45, Gertner does not specifically teach that the attachment element is configured to cause the reduction to be at least 10%. Gertner teaches a variety of attachment means that aid in restricting the stomach (para [0160]-[0163]). It would have been obvious to one skilled in the art that Gertner could be modified as claimed through routine experimentation in order to adjustably restrict food intake on a patient by patient basis.

Regarding claim 46, Gertner further teaches that the attachment element is configured to be coupled to the GI tract such that the element surrounds less than 270 degrees of the GI tract (para [0163]).

Regarding claim 47, Gertner further teaches that the attachment element comprises a clip (para [0156]).

Regarding claim 48, Gertner further teaches that the GI tract portion is a stomach of the subject, and wherein the attachment element is configured to be coupled to the stomach (para [0160]-[0163], fig. 11D).

Claims 1-5 lack an inventive step under PCT Article 33(3) as being obvious over US 2007/0027493 A1 to Ben-Haim et al. (hereinafter Ben-Haim) in light of US 2005/0069514 A1 to Starkebaum.

Regarding claim 1, Ben-Haim teaches an apparatus comprising:

- a) one or more fundic sensors, configured to be applied to a fundus of a subject, and to generate a fundic signal (para [0174], [0188], sensors 88 on the fundus); and
  - b) a control unit, configured to: make a determination of ingestion by the subject (para [0174], [0177], control unit 50), determine fundic impedance responsively to the fundic signal (para [0177], [0189]).
- Ben-Haim does not specifically teach calculate a duration of a period during which the fundic impedance rose during the tentatively-determined ingestion, and determine that the tentative determination of ingestion is a false positive upon finding that the duration is less than a fundic rise duration threshold value. Ben-Haim does teach determining ingestion false positives based on fundic impedance variance which is compared to a threshold value (para [0191], [0193], [0199]). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Starkebaum as claimed in order to more accurately determine false positives.

Regarding claim 2, Ben-Haim further teaches that the control unit is configured to make the determination of ingestion by interpreting an increase in fundic impedance vs. a baseline level greater than a fundic increase threshold value as indicative of the ingestion (para [0177], [0189], [0193]). While the determination is not tentative, Ben-Haim does appreciate detecting over a period of time and the elimination of false positives (para [0199], [0209]). It would have been obvious to one skilled in the art that Ben-Haim and Starkebaum could be modified as claimed in order to reduce false positives.

— see configuration sheet: —

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AL 08/0646

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:  
Box V.2 - Citations and explanations:

Regarding claim 3, Ben-Haim further teaches one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, wherein the control unit is configured to make the tentative determination of ingestion by determining an antral local sense responsively to the antral signal, and finding that the antral local sense is less than a local sense threshold value (para [0177], [0181], [0193]). Ben-Haim does not specifically teach monitoring the rate. Starkebaum further teaches monitoring the rate of change (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Starkebaum as claimed in order to more accurately determine false positives.

Regarding claim 4, Ben-Haim further teaches one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, wherein the control unit is configured to make the tentative determination of ingestion by determining an amplitude of antral contractions responsively to the antral signal, and finding that the antral contractions amplitude is greater than an antral contractions amplitude threshold value (para [0176], [0205]).

Regarding claim 5, Ben-Haim further teaches one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, wherein the control unit is configured to make the tentative determination of ingestion by: (b) a comparison of the antral contractions amplitude and an antral contractions amplitude threshold value (para [0176], [0193], [0205]). Ben-Haim does not specifically teach determining an antral local sense rate responsively to the antral signal, determining an amplitude of antral contractions responsively to the antral signal, and analyzing a combination of: (a) a comparison of the antral local sense rate with a local sense rate threshold value. Starkebaum further teaches monitoring the rate of change (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Starkebaum as claimed in order to more accurately determine false positives.

Claims 9, 20, 21 lack an inventive step under PCT Article 33(3) as being obvious over Ben-Haim in light of US 5,188,104 A to Wernicke et al. (hereinafter Wernicke).

Regarding claim 9, Ben-Haim teaches apparatus comprising:

- a) one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal (para [0174]; [0188], sensors 88 on the antrum); and
  - b) a control unit, configured to: detect ingestion of food by the subject (para [0174], [0177], control unit 90),
  - c) determine antral impedance responsively to the antral signal (para [0177], [0186]), and
  - d) interpret a change in antral impedance vs. a baseline value of less than a threshold value (para [0177], [0186], [0189], [0193]).
- Ben-Haim does not specifically teach the value as indicating that the ingested food is predominantly solid. Wernicke teaches an alternative system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Wernicke as claimed in order to modify the treatment more accurately in response to the food consumed.

Regarding claim 20, Ben-Haim teaches an apparatus comprising:

- a) a gastric band (para [0173], gastric device 28);
  - b) one or more gastrointestinal sensors, configured to be coupled to one or more gastrointestinal sites of a subject end to generate one or more gastrointestinal sensor signals responsive to a property of at least one of the gastrointestinal sites (para [0174], [0185], sensors 66 on the fundus); and
  - c) a control unit, configured to: receive and analyze the one or more gastrointestinal sensor signals (para [0174], [0177], control unit 90).
- Ben-Haim does not specifically teach to determine, responsively thereto, an extent to which ingested food includes solid food matter, and cause tightening of the gastric band in response to a determination that the ingested food includes predominantly the solid food matter. Wernicke teaches an alternative system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Wernicke as claimed in order to modify the treatment more accurately in response to the food consumed.

Regarding claim 21, Ben-Haim and Wernicke do not specifically teach that the one or more gastrointestinal sensors comprises one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, and wherein the control unit is configured to: detect ingestion of food by the subject, determine antral impedance responsively to the antral signal, and interpret a change in antral impedance vs. a baseline value of less than a threshold value as indicating that the ingested food includes predominantly the solid food matter. Ben-Haim does teach strum impedance sensors that measure relative to a threshold and baseline (para 0174; [0177], [0189], [0189], [0193]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim and Wernicke could be modified as claimed in order to modify the treatment more accurately in response to the food consumed.

Claims 6-8, 10-19, 22-54 lack an inventive step under PCT Article 33(3) as being obvious over Ben-Haim in light of Starkebaum and Wernicke.

Regarding claim 6, Ben-Haim and Starkebaum do not specifically teach that the control unit is configured to make a solid/liquid determination of whether the ingested food is predominantly solid or predominantly liquid. Wernicke teaches an alternative system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim and Starkebaum could be modified by the teaching of Wernicke as claimed in order to modify the treatment more accurately in response to the food consumed.

— see continuation sheet —

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/IL 06/00646

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.  
Continuation of  
Box V.2 - Citations and explanations:

Regarding claim 7, Ben-Haim further teaches a gastric band, wherein the control unit is configured to cause tightening of the gastric band respectively to the solid/liquid determination (para [0173], gastric device 26).

Regarding claim 8, Ben-Haim, Starkebaum and Wernicke do not specifically teach one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, wherein the control unit is configured to make the solid/liquid determination by: determining antral impedance responsively to the antral signal, calculating a correlation between changes in the antral impedance and changes in the fundic impedance over a period of time having a duration of between one and 10 minutes, and determining that the food is predominantly liquid upon finding that the correlation is greater than a threshold correlation value. Ben-Haim teaches antral sensors to detect impedance (para [0177], [0188], [0193]), Starkebaum teaches monitoring the rate of change over time (para [0016]-[0020]) and Wernicke teaches using such figures to determine solid or liquid food (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed in order to more accurately determine what is eaten and when.

Regarding claim 10, Ben-Haim teaches apparatus comprising:

a) one or more fundic sensors, configured to be applied to a fundus of the subject, and to generate a fundic signal (para [0174], [0188], sensors 68 on the fundus); and  
b) a control unit, configured to detect ingestion of food by the subject (para [0174], [0177], control unit 90), determine fundic impedance responsively to the fundic signal (para [0177], [0188]).  
Ben-Haim does not specifically teach calculate a duration of a period during which the fundic impedance rose during the ingestion, and determine that the ingested food is predominantly solid upon finding that the duration of the period is greater than a threshold value. Ben-Haim does teach determining ingestion based on fundic impedance variance which is compared to a threshold value (para [0191], [0193], [0199]). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0016]-[0020]). Wernicke teaches an alternative system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Starkebaum and Wernicke as claimed in order to more accurately determine false positives.

Regarding claim 11, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the threshold value is between one and five minutes. It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed through routine experimentation in order to more effectively rule out false positives caused for example by lying down.

Regarding claim 12, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the threshold value includes a first threshold value, and wherein the control unit is configured to determine that the ingested food is predominantly liquid upon finding that the duration of the period is less than a second threshold value. Ben-Haim teaches a variety of thresholds and baselines (para [0189], [0193]). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed through routine experimentation in order to differentiate between different foods more effectively.

Regarding claim 13, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the second threshold value is between 10 seconds and five minutes. It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed through routine experimentation in order to more effectively rule out false positives caused by other reasons.

Regarding claim 14, Ben-Haim teaches an apparatus comprising:

a) one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal (para [0174], [0188], sensors 68 on the antrum); and  
b) a control unit, configured to detect ingestion of food by the subject (para [0174], [0177], control unit 90).  
Ben-Haim does not specifically teach calculate an antral local sense rate responsively to the antral signal, and determine that the ingested food is predominantly liquid upon finding that a reduction in the rate over a period of time is greater than a first threshold value, the period of time commencing during the ingestion of the food and having a period duration of less than a second threshold value. Ben-Haim does teach determining ingestion based on fundic impedance variance which is compared to a threshold value (para [0191], [0193], [0199]). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0016]-[0020]). Wernicke teaches an alternative system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Starkebaum and Wernicke as claimed in order to more accurately determine false positives.

Regarding claim 15, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the period duration equals the duration of between one and three detected antral waves. It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed through routine experimentation in order to more effectively rule out false positives.

Regarding claim 16, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to receive an antral local sense baseline rate, and to set the first threshold value to be between 25% and 75% of the baseline rate. Ben-Haim teaches a variety of thresholds (para [0193]). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed through routine experimentation in order to more effectively rule out false positives.

Regarding claim 17, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to receive an antral local sense baseline rate, and to determine that the ingested food is predominantly liquid only upon finding that the reduction in the rate over the period of time is greater than the first threshold value, and that the rate returns to the baseline rate after a conclusion of the period of time. It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed through routine experimentation in order to more effectively rule out false positives.

— see continuation sheet —



-WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/IL 08/00646

**Supplemental Box**

In case the space is any of the preceding boxes is not sufficient.

Configuration of:  
Box V.2 - Citations and explanations:

Regarding claim 18, Ben-Haim teaches an apparatus comprising:

- a) one or more fundic sensors, configured to be applied to a fundus of a subject, and to generate a fundic signal (para [0174], [0180], sensors 68 on the fundus); and
  - b) a control unit, configured to: make a determination of ingestion of food by the subject (para [0174], [0177], control unit 90);
  - c) determine fundic impedance responsively to the fundic signal (para [0177], [0180]).
- Ben-Haim does not specifically teach calculate a maximum rise rate, expressible as a measure of resistance over a measure of time in the fundic impedance during at least one period of the ingestion, and determine that the ingested food is liquid upon finding that the rise is at least equal to a fundic rise threshold value. Ben-Haim does teach determining ingestion based on fundic impedance variation which is compared to a threshold value (para [0191], [0193], [0198]). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). Wernicke teaches an alternative system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Starkebaum and Wernicke as claimed in order to more accurately determine false positives.

Regarding claim 19, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the fundic rise threshold value is between one and 30 ohms per second. Ben-Haim does teach a threshold of 30 Ohms (para [0193]). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified as claimed in order to monitor ingestion more effectively.

Regarding claim 22, Ben-Haim and Wernicke do not specifically teach that the one or more gastrointestinal sensors comprise one or more fundic sensors, configured to be applied to a fundus of the subject, and to generate a fundic signal, and wherein the control unit is configured to: detect ingestion of food by the subject, determine fundic impedance responsively to the fundic signal, calculate a duration of a period during which the fundic impedance rose during the ingestion, and determine that the ingested food includes predominantly the solid food matter upon finding that the duration of the period is greater than a threshold value. Ben-Haim does teach fundic impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0180], [0189], [0193]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim and Wernicke could be modified by the teaching of Starkebaum as claimed in order to more effectively monitor the amount of ingestion.

Regarding claim 23, Ben-Haim and Wernicke do not specifically teach that the one or more gastrointestinal sensors comprise one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, and wherein the control unit is configured to: detect ingestion of food by the subject, calculate an entral local sense rate responsively to the antral signal, determine that the ingested food is predominantly liquid upon finding that a reduction in the rate over a period of time is greater than a first threshold value, the period of time commencing during the ingestion of the food and having a duration of less than a second threshold value, and cause loosening of the gastric band responsively to the determination that the ingested food is predominantly liquid. Ben-Haim does teach antrum impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0180], [0189], [0193]) to control loosening of a gastric device (para [0052], [0173]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim and Wernicke could be modified by the teaching of Starkebaum as claimed in order to more effectively monitor the amount of ingestion.

Regarding claim 24, Ben-Haim and Wernicke do not specifically teach that the one or more gastrointestinal sensors comprise one or more fundic sensors, configured to be applied to a fundus of a subject, and to generate a fundic signal, and wherein the control unit is configured to: make a determination of ingestion of food by the subject, determine fundic impedance responsively to the fundic signal, calculate a rise in the fundic impedance during at least one period of the ingestion, determine that the ingested food is liquid upon finding that the rise is at least equal to a fundic rise threshold value, and cause loosening of "the gastric" band responsively to the determination that "the ingested food is liquid. Ben-Haim does teach fundic impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0180], [0189], [0193]) to control loosening of a gastric device (para [0052], [0173]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim and Wernicke could be modified by the teaching of Starkebaum as claimed in order to more effectively monitor the amount of ingestion.

Regarding claim 25, Ben-Haim, Starkebaum and Wernicke do not specifically teach one or more current application electrodes configured to be coupled to a gastrointestinal tract of the subject, wherein the control unit is configured to drive a current to at least one of the one or more current application electrodes responsively to the extent to which the ingested food includes the solid food matter. Ben-Haim does teach electrodes into which current is driven (para [0188]) and Wernicke does teach determining the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim and Wernicke could be modified by the teaching of Starkebaum as claimed in order to more effectively monitor and control the amount of ingestion.

Regarding claim 26, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to drive the current only in response to the determination that the ingested food includes predominantly the solid food matter. Ben-Haim does teach electrodes into which current is driven (para [0188]) and Wernicke does teach determining the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim and Wernicke could be modified by the teaching of Starkebaum as claimed in order to more effectively monitor and control the amount of ingestion.

Regarding claim 27, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to begin driving the current before causing the tightening of the gastric band. Ben-Haim teaches electrodes into which current is driven (para [0188]) and adjusting the band (para [0173]). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified through routine experimentation as claimed in order to more effectively monitor and control ingestion.

-- see continuation sheet --

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/IL 08/00646

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.  
Continuation of  
Box V.2 - Citations and explanations:

Regarding claim 28, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to cause a first level of the tightening of the gastric band during a first period during which the control unit drives the current, and a second level of the tightening of the gastric band during a second period during which the control unit does not drive the current, the first level less than the second level. Ben-Haim does teach tightening of the gastric device (para [0173]). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified through routine experimentation as claimed in order to respond to further ingestion.

Regarding claim 29, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to cause a first level of the tightening of the gastric band during a first period during which the control unit drives the current, and a second level of the tightening of the gastric band during a second period during which the control unit does not drive the current, the first level greater than the second level. Ben-Haim does teach tightening of the gastric device (para [0173]). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified through routine experimentation as claimed in order to respond to further ingestion.

Regarding claim 30, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to drive the current only in response to a determination that the ingested food is predominantly liquid. Wernicke does teach determining the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified through routine experimentation as claimed in order to prevent patients bypassing the device by ingesting liquids only.

Regarding claim 31, Wernicke further teaches that the control unit is configured to cause the tightening of the gastric band at a timing configured to cause weight loss in the subject (col 14, in 1-9, triggered automatically at meal times).

Regarding claim 32, Ben-Haim further teaches that the control unit is configured to cause the tightening of the gastric band at a timing configured to control blood sugar in the subject (para [0149], [0233]).

Regarding claims 33 and 34, Ben-Haim, Starkebaum and Wernicke do not specifically teach that the control unit is configured to cause the tightening of the gastric band after a delay after making the determination that the ingested food includes predominantly the solid food matter, wherein the delay includes between 10 minutes and 30 minutes. Ben-Haim teaches a delay (para [0225]). Wernicke does teach determining the difference between solid and liquid ingestion (col 10, in 29-44). It would have been obvious to one skilled in the art that Ben-Haim, Starkebaum and Wernicke could be modified through routine experimentation as claimed in order to allow a set amount of normal ingestion.

Claims 35-36 lack an inventive step under PCT Article 33(3) as being obvious over Ben-Haim in light of Wernicke and US 2009/0064037 At to Shalon et al (hereinafter Shalon).

Regarding claim 35, Ben-Haim teaches an apparatus comprising:

a) one or more gastrointestinal sensors, configured to be coupled to one or more gastrointestinal sites of the subject and to generate one or more gastrointestinal sensor signals responsive to a property of at least one of the gastrointestinal sites (para [0174], [0177], [0168], sensors 88);

b) a control unit, coupled to the device communication module, and configured to: receive and analyze the one or more gastrointestinal sensor signals (para [0174], [0177], [0168], control unit 90). Ben-Haim does not specifically teach a handheld portable device, comprising a device wireless communication module, and configured to provide a food diary for a subject, for aiding in behavior modification related to food intake; an implantable wireless device communication module; and to determine, responsive thereto, an extent to which ingested food includes solid food matter, and drive the implantable wireless device communication module to wirelessly transmit, to the device wireless communication module, an indication of the extent to which the ingested food includes the solid food matter, wherein the handheld portable device is configured to record the indication in the food diary. Wernicke teaches determining the difference between solid and liquid ingestion (col 10, in 29-44). Shalon teaches a system which notably includes a wireless handheld device which receives GI data and records a food log (para [0098], [0145], [0221]). It would have been obvious to one skilled in the art that Ben-Haim could be modified by the teaching of Wernicke and Shalon as claimed in order to provide feedback to the patient as to the effects of eating certain foodstuffs.

Regarding claim 36, Shalon further teaches that the behavior modification includes weight loss, and wherein the food diary is configured to aid in the weight loss (para [0197]).

Claims 37-43 lack an inventive step under PCT Article 33(3) as being obvious over Ben-Haim in light of Wernicke, Shalon and Starkebaum.

Regarding claim 37, Ben-Haim, Wernicke and Shalon do not specifically teach that the one or more gastrointestinal sensors comprise one or more entral sensors, configured to be applied to an entrum of the subject, and to generate an entral signal, and wherein the control unit is configured to: detect ingestion of food by the subject, determine entral impedance responsively to the entral signal, and interpret a change in entral impedance vs. a baseline value of less than a threshold value as indicating that the ingested food includes predominantly the solid food matter. Ben-Haim does teach entral impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0168], [0189], [0193]) to control loosening of a gastric device (para [0052], [0173]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, in 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke and Shalon could be modified by the teaching of Starkebaum as claimed through routine experimentation in order to more effectively monitor the amount of ingestion.

— see continuation sheet —

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 08/00646

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:  
Box V-2 - Citations and explanations:

Regarding claim 38, Ben-Haim, Wernicke and Shalon do not specifically teach that the one or more gastrointestinal sensors comprise one or more fundic sensors, configured to be applied to a fundus of the subject, and to generate a fundic signal, and wherein the control unit is configured to detect ingestion of food by the subject, determine fundic impedance responsively to the fundic signal, calculate a duration of a period during which the fundic impedance rose during the ingestion, and determine that the ingested food includes predominantly the solid food matter upon finding that the duration of the period is greater than a threshold value. Ben-Haim does teach fundic impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0188], [0189], [0193]) to control loosening of a gastric device (para [0052], [0173]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, ln 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke and Shalon could be modified by the teaching of Starkebaum as claimed through routine experimentation in order to more effectively monitor the amount of ingestion.

Regarding claim 39, Ben-Haim, Wernicke and Shalon do not specifically teach that the one or more gastrointestinal sensors comprise one or more antral sensors, configured to be applied to an antrum of the subject, and to generate an antral signal, and wherein the control unit is configured to detect ingestion of food by the subject, calculate an antral solid sense rate responsively to the antral signal, and determine that the ingested food is predominantly liquid upon finding that a reduction in the rate over a period of time is greater than a first threshold value, the period of time commencing during the ingestion of the food and having a duration of less than a second threshold value. Ben-Haim does teach antrum impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0188], [0189], [0193]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, ln 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke and Shalon could be modified by the teaching of Starkebaum as claimed through routine experimentation in order to more effectively monitor the amount of ingestion.

Regarding claim 40, Ben-Haim, Wernicke and Shalon do not specifically teach that the one or more gastrointestinal sensors comprise one or more fundic sensors, configured to be applied to a fundus of a subject, and to generate a fundic signal, and wherein the control unit is configured to make a determination of ingestion of food by the subject, determine fundic impedance responsively to the fundic signal, calculate a rise in the fundic impedance during at least one period of the ingestion, and determine that the ingested food is liquid upon finding that the rise is at least equal to a fundic rise threshold value. Ben-Haim does teach fundic impedance sensors that measure relative to a threshold and baseline (para [0174], [0177], [0188], [0189], [0193]) to control loosening of a gastric device (para [0052], [0173]). Wernicke teaches a system which notably can determine the difference between solid and liquid ingestion (col 10, ln 29-44). Starkebaum teaches an alternative system which notably monitors the rate of change of the impedance (para [0018]-[0020]). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke and Shalon could be modified by the teaching of Starkebaum as claimed through routine experimentation in order to more effectively monitor the amount of ingestion.

Regarding claim 41, Ben-Haim, Wernicke, Shalon and Starkebaum do not specifically teach that one or more current application electrodes configured to be coupled to a gastrointestinal tract of the subject, wherein the control unit is configured to drive a current to at least one of the one or more current application electrodes responsively to the extent to which the ingested food includes the solid food matter. Ben-Haim does teach electrodes into which current is driven (para [0188]) and Wernicke does teach determining the difference between solid and liquid ingestion (col 10, ln 29-44). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke, Shalon and Starkebaum could be modified as claimed through routine experimentation in order to more effectively monitor and control the amount of ingestion.

Regarding claim 42, Ben-Haim, Wernicke, Shalon and Starkebaum do not specifically teach that the control unit is configured to drive the current only in response to a determination that the ingested food includes predominantly the solid food matter. Ben-Haim does teach electrodes into which current is driven (para [0188]) and Wernicke does teach determining the difference between solid and liquid ingestion (col 10, ln 29-44). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke, Shalon and Starkebaum could be modified as claimed through routine experimentation in order to more effectively monitor and control the amount of ingestion.

Regarding claim 43, Ben-Haim, Wernicke, Shalon and Starkebaum do not specifically teach that the control unit is configured to drive the current only in response to a determination that the ingested food is predominantly liquid. Ben-Haim does teach electrodes into which current is driven (para [0188]) and Wernicke does teach determining the difference between solid and liquid ingestion (col 10, ln 29-44). It would have been obvious to one skilled in the art that Ben-Haim, Wernicke, Shalon and Starkebaum could be modified as claimed through routine experimentation in order to more effectively monitor and control the amount of ingestion.

Claims 1-48 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:  
SANDFORD T. COLB & CO.  
P.O. BOX 2273  
76122 REHOVOT  
ISRAEL

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing 28 OCT 2008  
(day/month/year)

Applicant's or agent's file reference  
65343

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.  
PCT/IL 08/0646

International filing date 11 May 2008 (11.05.2008)  
(day/month/year)

Applicant METACURE LTD.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transcribed herewith.  
Filing of amendments and statement under Article 19:  
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):  
When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.  
Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35  
For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:  
☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

### 4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 871-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 871-273-4300  
PCT ODP: 871-272-7774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

# NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers;  
claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

## "Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)). The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)".

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

## Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/PEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1(b)(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43 bis.1(c)).

## Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.